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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,581

12/08/2004

Rafael Ferritto Crespo

X-14844

1754

25885

7590

06/28/2006

ELI LILLY & COMPANY

PATENT DIVISION

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EXAMINER

MOORE, SUSANNA

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/517,581	<b>Applicant(s)</b> FERRITTO CRESPO ET AL.	
	<b>Examiner</b> Susanna Moore	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 12, 14-18, 20-23, 25-28, 30, 32-34, 36 and 40-45 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9, 11, 12, 14-18, 20-23, 25-28, 30, 32-34, 36 and 40-45 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group (I), claim(s) 1-3, 11, 15-18, 20, 21, 23, 25, 30, 32-34, 36 and 43 are drawn to compounds of formula (I) wherein NR1R2 form a piperazine ring, compositions and methods of treatment thereof.

Group (II), claim(s) 1-3, 11, 15-18, 20-22, 30, 32-34, 36 and 43, drawn to compounds wherein NR1R2 form a piperidine ring, compositions and methods of treatment thereof.

Group (III), claim(s) 1-3, 11, 15-18, 20, 21, 30, 32-34, 36 and 43, drawn to compounds wherein NR1R2 form a dihydroisoquinoline ring, compositions and methods of treatment thereof.

Group (VI), claim(s) 1-3, 15-18, 20, 21, 30, 32-34, 36 and 43, drawn to compounds not found in groups (I-III) wherein NR1R2 form another heterocyclic ring, compositions and methods of treatment thereof.

Group (V), claim(s) 1-5, 7, 9, 12, 15-18, 20, 21, 30, 32-34, 36, 41 and 43, drawn to compounds wherein R2 is a thiadiazole, compositions and methods of treatment thereof.

Group (VI), claim(s) 1-5, 7, 9, 15-18, 20, 21, 30, 32-34, 36, 41 and 43, drawn to compounds wherein R2 is a thiazole, compositions and methods of treatment thereof.

Group (VII), claim(s) 1-5, 7, 9, 12, 15-18, 20, 21, 30, 32-34, 36, 41 and 43, drawn to compounds wherein R2 is a benzothiazole, compositions and methods of treatment thereof.

Group (VIII), claim(s) 1-5, 7, 9, 12, 15-18, 20, 21, 26, 27, 30, 32-34, 36, 41 and 43, drawn to compounds not found in groups (V-VII) wherein R2 is another heterocyclic ring, compositions and methods of treatment thereof.

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Group (IX), claim(s) 1-6, 9, 14-18, 20, 21, 26-28, 30, 32-34, 36 and 40-45, drawn to compounds wherein R2 is a non-heteroamide moiety, compositions and methods of treatment thereof.

Note: If group (VII) is elected then election of a single disclosed species is required.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) Group I -Group X lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The technical feature corresponding to the claims is the heterocycle ring connecting R1 and R2 or at R2 providing inhibitors of PPAR. Group (I) contains compounds with a piperzine ring connecting R1 and R2. Group (II) contains compounds with a piperidine ring connecting R1 and R2. Group (III) contains compounds with a dihydroisoquinoline ring between R1 and R2. Group (IV) contains compounds not encompassed by groups (I-III) with a heterocyclic ring between R1 and R2, e.g. morpholine. Group (V) provides compounds with a thiadizole at R2. Group (VI) provides compounds with a thiazole at R2 and group (VII) provides compounds with a benzothiazole at R2. Group (VIII) encompasses compounds not included in groups (V-VII) with a heterocyclic ring at R2, e.g. oxazole. Group (IX) contains all compounds with non-hetero amides.

Therefore claims 1-9, 11, 12, 14-18, 20-23, 25-28, 30, 32-34, 36 and 40-45 are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature.

The variables on the 2-phenoxyacetamide scaffold vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to only a product, compositions and a method of treatment.

Furthermore, in regards to groups I-IX even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

And, according to 37 CFR 1.475(c)

if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

Therefore, since the claims are drawn to more than a product, a composition, and a method of use, and according to 37 CFR 1.475 (e)

the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The claims, therefore, lack unity of invention.

### *Election*

A telephone call was made to Macharri Vorndran-Jones on June 13, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made. A written requirement was requested.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

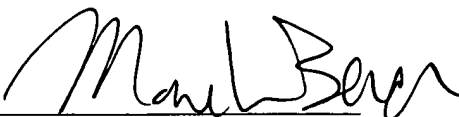
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Moore whose telephone number is (571) 272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Mark L. Berch  
Primary examiner

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